**GUDID Data Summary**

This summary is based on the accessed data on 6/28/2018, which is located “U:\Division of Epidemiology\BIA-ALCL-project\ontology\AccessGUDID\_6-28-2018\0\_allSheets.xlsx”.

The goal of this summary is facilitating the understanding of the data structure, to further assist the ontology development.

This summary is only the summary statistics of each column in each table (or sheet in excel, will be called table thereafter).

# 1. Table “device”

There are 1744 rows and 29 columns in the table. The following are the column names:

'PrimaryDI', 'deviceRecordStatus', 'devicePublishDate',

'deviceCommDistributionEndDate', 'deviceCommDistributionStatus',

'brandName', 'versionModelNumber', 'catalogNumber', 'companyName',

'deviceCount', 'deviceDescription', 'DMExempt', 'premarketExempt',

'deviceHCTP', 'deviceKit', 'deviceCombinationProduct', 'singleUse',

'lotBatch', 'serialNumber', 'manufacturingDate', 'expirationDate',

'donationIdNumber', 'labeledContainsNRL', 'labeledNoNRL',

'MRISafetyStatus', 'rx', 'otc', 'deviceSterile',

'sterilizationPriorToUse'

## deviceRecordStatus

only one value: 'Published'

## devicePublishDate

only possible dates:

|  |  |
| --- | --- |
| value | frequency |
| 9/17/2014 | 630 |
| 10/23/2015 | 211 |
| 10/4/2016 | 200 |
| 2/28/2018 | 109 |
| 1/12/2017 | 96 |
| 1/13/2017 | 59 |
| 10/10/2014 | 52 |
| 5/12/2015 | 52 |
| 5/11/2015 | 47 |
| 7/7/2016 | 45 |
| 1/11/2017 | 45 |
| 11/20/2014 | 43 |
| 8/31/2017 | 43 |
| 2/19/2018 | 43 |
| 8/24/2017 | 28 |
| 9/10/2015 | 23 |
| 9/9/2015 | 15 |
| 7/19/2017 | 1 |
| 5/8/2015 | 1 |
| 10/13/2015 | 1 |

## deviceCommDistributionStatus

all of them are “In Commercial Distribution”

## brandName

There are 26 unique values. They are:

|  |  |
| --- | --- |
| value | frequency |
| SIENTRA Silicone Gel Breast Implant | 285 |
| MENTOR MemoryGel Breast Implant | 263 |
| Natrelle Inspira Cohesive Breast Implants | 200 |
| Natrelle Inspira SoftTouch Breast Implants | 200 |
| Natrelle INSPIRA Breast Implants | 197 |
| NATRELLE Silicone-Filled Breast Implants | 143 |
| NATRELLE 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants | 112 |
| NATRELLE Saline-Filled Breast Implants | 103 |
| MENTOR MemoryShape Breast Implant | 79 |
| MENTOR MemoryGel Xtra Breast Implant | 43 |
| MENTOR Smooth Round Moderate Plus Profile | 20 |
| MENTOR Smooth Round Moderate Profile | 17 |
| MENTOR Smooth Round High Profile | 15 |
| MENTOR SILTEX Round Moderate Profile | 13 |
| IDEAL IMPLANT | 14 |
| MENTOR Smooth Round SPECTRUM | 10 |
| MENTOR SILTEX Round SPECTRUM | 8 |
| MENTOR SILTEX CONTOUR PROFILE Moderate | 6 |
| MENTOR SILTEX CONTOUR PROFILE High | 5 |
| MENTOR SILTEX CONTOUR PROFILE SPECTRUM | 5 |
| MENTOR Diaphragm Valve Fill Tube LONG 61cm 24in with 45 Degree Connector | 1 |
| MENTOR Diaphragm Valve Fill Tube with 45 Degree Connector | 1 |
| MENTOR Injection Domes with Stainless Steel TRUE LOCK Connection Systems | 1 |
| MENTOR Diaphragm Valve Fill Tube | 1 |
| MENTOR Diaphragm Valve Fill Tube LONG 61cm 24in | 1 |
| Diaphragm Valve Fill Tube and Reflux Valve | 1 |

## versionModelNumber

all of them are different from each other

## catalogNumber

all of them are different from each other

## companyName

There are four companies in the data:

|  |  |
| --- | --- |
| companyName | frequency |
| Allergan, Inc. | 956 |
| MENTOR TEXAS L.P. | 489 |
| Sientra, Inc. | 285 |
| IDEAL IMPLANT INCORPORATED | 14 |

## deviceDescription

most of the are unique values. See the table below. There are 56 descriptions appear twice, 5 descriptions appear 3 times, 5 descriptions appear 4 times, 2 descriptions appear 5 times, and one description appear 14 times.

|  |  |
| --- | --- |
| times | number of descriptions |
| 1 | 1573 |
| 2 | 56 |
| 4 | 5 |
| 3 | 5 |
| 5 | 2 |
| 14 | 1 |

## deviceCommDistributionEndDate, DMExempt, premarketExempt, deviceHCTP, deviceCombinationProduct, labeledContainsNRL, otc, sterilizationPriorToUse

These columns are all empty.

## deviceKit

203 are marked as “True”, the rest are empty.

## singleUse

all of them are “True”

## lotBatch

491 are marked as “True”, the rest are empty.

## serialNumber

all of them are “True”

## manufacturingDate

3 are marked as “True”, the rest are empty.

## expirationDate

all of them are “True”

## donationIdNumber

1 is marked as “True”, the rest are empty.

## labeledNoNRL

1053 are marked as “True”, the rest are empty.

## MRISafetyStatus

Two existing values:

|  |  |
| --- | --- |
| MR Safe | 1241 |
| Labeling does not contain MRI Safety Information | 503 |

## rx

1742 are marked as “True”, the rest are empty.

## deviceSterile

1743 are marked as “True”, the rest is empty.

# 2. Table “deviceSizes”

The columns in this table:

'PrimaryDI', 'sizeType', 'size (Unit)', 'size (Value)', 'sizeText'

## sizeType

Size type are all “Device Size Text, specify”

## 'size (Unit)', 'size (Value)'

They are all empty in this table

## size (Value)

There are 245 possible values. Below is the list of top values which are bigger than 14. [please contact me if you need me to pull out the full list.]

|  |  |
| --- | --- |
| size | frequency |
| 560 cc | 28 |
| 240 cc | 21 |
| 360 cc | 21 |
| 200 cc | 21 |
| 650 cc | 19 |
| 400 cc | 19 |
| 320 cc | 18 |
| 300 cc | 17 |
| 220 cc | 16 |
| 140 cc | 16 |
| 450 cc | 15 |
| 125 cc | 15 |

# 3. Table “productCodes”

There are 3 columns: 'PrimaryDI', 'productCode', 'productCodeName'

## productCode

|  |  |
| --- | --- |
| productCode | frequency |
| FTR | 1523 |
| FWM | 221 |

## productCodeName

|  |  |
| --- | --- |
| productCodeName | frequency |
| Prosthesis, Breast, Noninflatable, Internal, Silicone Gel-Filled | 1138 |
| Prosthesis, breast, noninflatable, internal, silicone gel-filled | 385 |
| Prosthesis, Breast, Inflatable, Internal, Saline | 117 |
| Prosthesis, breast, inflatable, internal, saline | 104 |